oriGIn
Organisation for an International
Geographical Indications Network

Mr. Martial PLANTADY

European Commission
Directorate General for Health and Consumer Protection
B-1049 Brussels
Belgium

Geneva, 14 July 2014

RE: Draft guidance on the application of article 14 of regulation (EC) n° 178/2002 with regard to food where shiga-toxin producing *Escherichia coli* (STEC) is detected

Dear Mr Plantady,

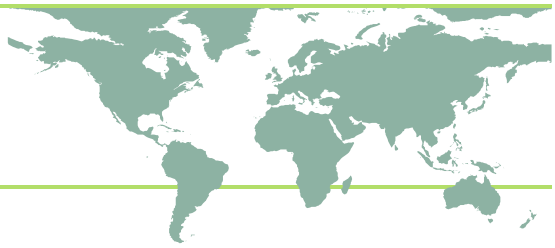
The Organization for an International Geographical Indications Network (oriGIn) is the global alliance of Geographical Indications (GIs), representing today some 350 groups and over two-million producers. oriGIn advocates for the effective legal protection and enforcement of GIs at the national, regional and international level.

As major differences exist among European countries in the management of STEC alerts, oriGIn welcomes the recent initiative of DG Sanco aimed to harmonize the management of STEC-related risks.

Having said that, we believe that the overall approach of the draft guidance on the application of article 14 of regulation (EC) n° 178/2002 with regard to food where STEC is detected – in particular defining unsafe food based only on the detection of shigatoxins producing strains – raises several concerns:

- Ruminants are healthy carriers of STEC and animal food could be potentially contaminated with these bacteria. STECs comprise over 2.000 serotypes that differ greatly in both their physiological characteristics and their pathogenic potential to humans. **Not all STEC serotypes are pathogenic and only a relatively small number of the entire family of STEC is pathogenic**. As a result, a consensus on a scientific definition of pathogenic STECs is urgently needed, as well as a coherent strategy to define the set of pathogenicity.

- Based on available scientific knowledge, the European Food Safety Authority (EFSA), in its opinion of April 2013, as well as the American Food Safety and Inspection Service, have chosen to screen food samples by strain isolation of the main pathogenic serogroups in combination with few virulence markers.



- The International Standardization Organization (ISO) has developed a method for detection of STEC in food (ISO- TS 13136:2012): samples are enriched and screened by real-time PCR for *stx, eae* genes and for the presence of the "most dangerous five" serogroups O157, O111, O26, O103 and O145. Following this approach, strain isolation – as indicated in the above-mentioned draft guidance – is not recommended in the first step of food analysis. According to the EFSA, an alternative approach to the ISO one, simply based on the detection of verocytotoxins alone or gene encoding such verotoxins, does not provide a sound scientific basis on which to assess risk for the consumer.

- A few sporadic cases and rare outbreaks caused by different STEC serogroups are identified due to ingestion of milk products. We consider that there is probably an impact of matrices and processes on the expression of virulence factors that reduce the virulence of STEC strains potentially present in dairy products. Many studies are underway to understand the behavior of STEC and the expression of virulence factors in cheeses and during digestion.

- We are skeptical about a "high/low risk products" classification. STEC risk management should be part of the Hazard Analysis and Critical Control Points (HACCP) approach. Operators have to consider STEC as a risk based on their hygiene practices, technological processes and the end use of their products.

- With specific regard to the occurrence of STEC in dairy products, available analytical methods only aim at detecting virulence factors, such as *stx1, stx2, eae*. The available data show that the occurrence of *stx* genes in cheeses made with raw milk may vary from 5 to 30%, according to the cheese processes. Thus, if only *stx* genes are looked at, several products would be considered unsafe without having any real health risk. The consequence of this approach is economically disastrous for dairies. In this respect, **we would like to recall that the raw milk based dairy sector represents a key factor of dynamisms in the European economy. As a way of example, the raw milk based cheese production in France reached 180.737 tons in 2012 (corresponding to the 15% of the overall cheese production; As for raw milk sheep cheese, it corresponds to 35,6% of the overall cheese production in the same year). Within the cheese sector, Protected Designation of Origin (PDO) and Protected Geographical Indication (PGI), registered under Regulation (EU) 1151/2012 on the protection of Geographical Indications and Designations of Origin for agricultural products and foodstuffs, play a key role. As PDO and PGI identify products intimately linked to a**

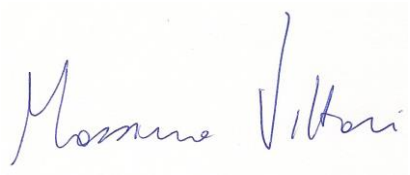
specific geographical area, raw milk is widely used in PDO/PGI cheeses. Raw milk often represents a fundamental element to ensure the unique qualities, taste and other specificities of the European PDO/PGI cheeses, which are largely researched and appreciated by consumers both in the internal market and outside the European Union. Consumers also appreciate the cultural heritage behind such PDO/PGI cheeses, for which the raw milk is a crucial component. In terms of economic impact of such products, in 2012 the French PDO cheeses based on raw milk accounted for 142.000 tons (80% of the overall national raw milk cheese production). Out of the 45 French PDO cheeses (which represent a turnover of 1.8 billion Euros per year at the different stages of the production chain), 26 have indicated raw milk as part of their product specification, and would therefore be negatively affected by the draft guidelines on the application of article 14 of regulation (EC) n° 178/2002 with regard to food where STEC is detected. Such PDO represent 126.000 tons of cheese and 8.500 milk producers.

To conclude, we believe a harmonized approach to manage the risk of STEC in food in the European Union is needed. However, the mere risk presumption - defined by the sole presence of the gene marker *stx* in an isolate –does not represent in our view the right approach and would have disastrous consequences for dairy GI sector in the European Union. **We would rather recommend the European Commission to develop guidelines that focus on the definition of a dangerous serotypes shortlist.**

In this respect, the European members of oriGIn would be delighted to meet with you in Brussels at your earliest convenience and discuss the above-mentioned issues.

Meanwhile, we remain at your complete disposal, should you require any further information.

Sincerely yours,



Managing Director, oriGIn

CC: Mr. Michael ERHART, Head of Unit, Agricultural product and quality policy, European Commission's Directorate-General for Agriculture and Rural Development